PTO/SB/08B (04-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Substitute for form 1449/P1

Applicati n Number 10/635,807

Filling Dat August 5, 2003

First Named Inventor RUBENSTEIN, EDWARD, et. al.

Art Unit Unassigned

Examiner Name Unassigned

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 Attomey Docket Number
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U.S. PATENT DOCUMENTS						
		Document Number				
Examiner	Cite No.1	Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
QUB.	Α	3,654,932	04/1972	Newkirk et al.		
	В	3,864,259	02/1975	Newhart		
	С	3,886,948	06/03/75	Hakim		
	D	4,156,422	05/29/79	Hildebrandt et al.	\	
	Е	4,261,341	04//1981	Hakim et al.		
	F	4,375,816	03/08/83	Labianca		
	G	4,560,375	12/24/85	Schulte et al.		
	Н	4,598,579	07/08/86	Cummings et al.		
	I	4,605,395	08/12/86	Rose et al.		
	J	4,610,658	09/1986	Buchwald et al.		
	K	4,673,384	06/16/87	Marion		
	L	4,675,003	06/1987	Hooven		
	M	4,681,559	07/1987	Hooven	\	
	N	4,713,065	12/1987	Koot		
	0	4,933,156	06/12/90	Quay et al.		
	P	4,950,232	08/21/90	Ruzicka et al.	·	
	. Q	5,039,511	08/13/91	Quay		
	R	5,069,663	12/1991	Sussman		
	S	5,167,615	12/1992	East et al.		
	Т	5,334,315	08/02/94	Matkovich et al.		
	U	5,336,166	08/09/94	Sierra		
	V	5,368,556	11/1994	Lecuyer		
1	W	5,385,541	01/31/95	Kirsch et al.		
RUS	Х	5,387,188	02/07/95	Watson	-	

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<u>sll</u>	Y	5,425,368	06/20/95	Brandt		
<u> </u>	Z	5,462,667	10/31/95	Wollinsky et al.		
	AA	5,601,985	02/11/97	Trojanowski et al.		
	BB	5,643,194	07/1997	Negre		
	CC	5,643,195	07/1997	Drevet et al.		
(DD)	AA	5,980,480	11/1999	Rubenstein et al.		
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					FOREIGN PA	TENT DOCUME	ENTS		
Examiner		Čia-	Foreign Patent Document			Name of Patentee or	Pages, Columns, Lines,		
Initials*	Cite No.1	Country Code ³	Number ⁴	Kind Code ^k (# known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	т⁰	
al	9	AB	FR2685206	06/1993	France				
		AC	EP 478842	04/1992	Europe				
		AD	EP 117695	09/1984	Europe			_	
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Substitute for form 1449/PTO Compl te if Kn wn Applicati n Number 10/635,807 INFORMATION DISCLOSURE Filing Date August 5, 2003 STATEMENT BY APPLICANT First Named Inventor RUBENSTEIN, EDWARD, et. al. **Art Unit** Unassigned (use as many sheets as necessary) **Examiner Name** Unassigned Page of Attorney Docket Number 018050-000140US

		FOREIGN PA	TENT DOCUME	ENTS				
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code 3 Number 4 Kind Code (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T°		
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Examiner Initials *	Cite No.1	Include name of the author (In CAPITAL LE item (book, magazine, journal, serlal, s number(s), publisher,	ymposium, catalo	g, etc.), date, page(s), vo		T 2		
Plp	AG	Adams et al., "Disturbances of cerebro and meningeal reactions," <i>Principles of</i> 501-502.						
	AH	Adams, R.D. et al., "Symptomatic occupressure" <i>The New England Journal of</i> 15, 1965).	•		•			
	AI Appenzeller, Otto & Salmon, James H., "Treatment of parenchymatous degeneration of the brain by ventriculo-atrial shunting of the cerebrospinal fluid, <i>Journal of Neurosurgery</i> , Volume XXVI, pages 478-482, (January-June 1967).							
	AJ	Arai et al., "Tau in cerebrospinal fluid: vol. 38, 1995, pp. 649-652.	a potential dia	gnostic marker," Ann	. Neurology,			
AK Bannister, Roger, et al., "Isotope encephalography in the diagnosis of dementia due to communicating hydrocephalus" <i>The Lancet</i> , pgs. 1014-1017, (November 11, 1967).								
	AL	Barnett et al., "Normal pressure hydroc Neurosurgery (1987) 20(6):904-907.	ephalus in child	iren and young adults	,			
	AM	Boon et al., "Does CSF outflow resista: with normal pressure hydrocephalus?"			n patients			
	AN	Boon et al., "Dutch normal-pressure hy shunting by resistance to outflow of cer 693.						
	AO	Bush et al., "Beta A-4 amyloid protein Pharmac. Tera., Vol. 56, 1992, pp. 97-		or in Alzheimer's dise	ase,"	1		

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Examiner Signature	Deroud	Date Considered	11-14-821

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Complete if Known Applicati n Number 10/635,807 Filing Date August 5, 2003 First Named Inventor RUBENSTEIN, EDWARD, et. al. Art Unit Unassigned **Examiner Name** Unassigned

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		FOREIGN PAT	TENT DOCUME	ENTS			
Examiner Initials*	Cite No.1	Foreign Patent Document Number ⁴ Country Code ³ Nind Code ⁴ (If known)	Publication Date Name of Patentee or When MM-DD-YYYY Applicant of Cited Passage		Pages, Columns, Line Where Relevant Passages or Relevar Figures Appear	`	
XVB	AP	Chen, I.H. et al., "Effectiveness of shur hydrocephalus predicted by temporary, a pilot study," Journal of Neurology, N	controlled-resi	stance, continuous lui	mbar drainage:	!	
	AQ	Clarfield, "Normal-pressure hydroceph 262(18):2592-2593.	alus: Saga or sv	wamp?" <i>JAMA</i> (1989)		
	AR	Damasceno et al., "The predictive value of cerebrospinal fluid tap-test in normal pressure hydrocephalus" Arq. Neurosiquiatr. (1997) 55(2):179-185.					
	AS	Friedland, "Normal-pressure hydrocephalus and the saga of the treatable dementias" JAMA (1989) 262(18):2577-2581.					
	AT Golomb et al., "Alzheimer's disease comorbidity in normal pressure hydrocephalus: prevalence and shunt response" J. Neurol. Neurosurg. Psych. (2000) 68:778-781.						
	AU	Graff-Radford et al., "Normal-pressure	hydrocephalus	" Neurol. (1986) 43:9	40-942.		
	AV	Gustafson et al., "Recovery in hydrocep Neurosurg. Psych. (1978) 41:940-947.	halic dementia	after shunt operation	" J. Neurol.		
	AW	Hakim et al., "The special clinical prob cerebrospinal fluid pressure. Observati <i>Neurol. Sci.</i> (1965) 2:307-327.	lem of sympton ons on cerebros	natic hydrocephalus v spinal fluid hydrodyna	vith normal amics" J.		
	AX	Holodny et al., "Focal dilation and para patients with normal-pressure hydrocep					
	AY	Kaye et al., "Plasticity in the aging brain	n" Arch Neuro	<i>l.</i> (1990) 47:1336-134	1 1.		
1	AZ	Ko et al., "Cerebrospinal fluid control s pp. 1226-1235, September 1988.	ystem" Proceed	lings of the IEEE, Vo	l. 76, No. 9,		
BA Martinez et al., "Relationship of interleukin-1 beta and beta ₂ -microglobulin with neuropeptides in cerebrospinal fluid of patients with dementia of the Alzheimer type," J. Neuroimmunology, Vol. 48, 1993, pp 235-240.						\int	

Examiner Signature	Delsjona	Date Considered	11-14-04

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RUB	BB	Mataró et al., "Cognitive changes after of spina bifida and assumed arrested hydro 68:615-621.	cerebrospinal focephalus" J. A	luid shunting in youn leurol. Neurosurg. Ps	g adults with ych. (2000)	1		
	BC	Mogilner et al., "Hydorcephalus: Does of Poster Presentation from AANS 1999 N total.	coexistent Alzh ew Orleans, ht	neimer's disease affectp://cnshome.org/abs	t outcome?" trats, 2 pages			
	BD	Nakamura et al., "Amyloid beta protein levels in cerebrospinal fluid are elevated in early-onset Alzheimer's disease," Ann. Neurology, Vol. 36, 1994, pp. 903-911.						
	BE Ono et al., "Formation of amyloid-like substance from beta-2-microglobulin in vitro. Role of serum amyloid P component: a preliminary study," Nephron. Vol. 66, 1994, pp. 404-407.							
	BF	Salmon, James H., "Senile and presentle 67-72.	dementia" G	eriatrics (December 1	1969) 24 (12) :		_	
	BG	Shenkin et al., "Ventricular shunting for 225(12):1486-1489.	relief of senile	symptoms" JAMA (1973)		_	
	ВН	SkinhØj, Erik, "Determination of region conference proceedings, held at the Univ Education with Joseph P. Evans as host.	ersity of Chica	ago Center for Contin	d injury wing			
	BI	Vanneste et al., "Shunting normal-pressi risks?" Neurol. (1992) 42:54-59.	ire hyrocephal	us: Do the benefits or	tweigh the			
	BJ	Vorstrup et al., "Cerebral blod flow in pa before and after shunting" J. Neurol. (19	atients with no 987) 66:379-38	rmal-pressure hydroc	ephalus			
U	BK	Williams et al., "Evaluation of shunt fun than worse after shunt surgery for NPH"	ction in patien	ts who are never bette	er, or better 0.			
SUP	BL Williams et al., "Comparison of Pcsf monitoring and controlled CSF drainage diagnose normal pressure hydrocephalus" Acta Neurochir. (1998) 71:328-330.							

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